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**An Analysis and Evaluation of  
Certificate of Need Regulation in Maryland  
Ambulatory Surgical Facilities and Services**

*Response to Written Comments on the  
Staff Recommendation*

**MARYLAND HEALTH CARE COMMISSION**

**December 20, 2001**

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# **An Analysis and Evaluation of Certificate of Need Regulation in Maryland: Ambulatory Surgical Facilities and Services**

## ***Response to Written Comments on the Staff Recommendation***

### **I. Introduction**

The Maryland Health Care Commission's working paper, titled *An Analysis and Evaluation of Certificate of Need Regulation in Maryland: Ambulatory Surgical Facilities and Services*, was developed as one in a series of working papers examining major policy issues of the Certificate of Need (CON) process, as required by House Bill 995 (1999). The paper presented, for review and comment, alternative CON program policy options (Options 1 through 5 below) and actions related to regulation of ambulatory surgical facilities that could be taken within a range of CON program configurations (Options 6 through 8 below).

**Option 1:** Maintain the existing scope of CON regulation

**Option 2:** Modify the existing scope of CON regulation with two changes

- Eliminate CON requirements for expansion of outpatient operating room capacity
- Eliminate potential for establishment of 2-operating room freestanding ambulatory surgical facilities through CON exemption

**Option 3:** Expand CON regulation to regulate establishment of any surgical facility or the addition of any operating rooms or procedure rooms by existing facilities

**Option 4:** Expand CON regulation to regulate establishment of any surgical facility providing services within a sterile operating room or the addition of any operating rooms by existing facilities

**Option 5:** Eliminate all CON regulation of surgical facilities and services

**Option 6:** Expand data collection from freestanding ambulatory surgical facilities

**Option 7:** Expand licensure of freestanding ambulatory surgical facilities to cover all such facilities without regard to payment source

**Option 8:** Establish consistent definitions of surgical facilities and their components across licensure and CON regulation

The Commission released the working paper on September 19, 2001, and invited the submission of comments from interested organizations and individuals through October 19, 2001. Eleven written comments were received. None of the five program policy options received explicit support from a majority of the commenters. Option 1, leaving the current scope of CON regulation in place, received the most support (5 commenters) and was not explicitly opposed by any. The other four program policy options all received more explicit opposition than support. Of the other three options, Option 7 (expanding the scope of medical facilities licensure to cover all types of surgical facilities) and Option 8 (establishing consistent definitions of surgical facility room inventories) received explicit support from 5 and 6 commenters, respectively, and no explicit opposition. Expanding data collection from ambulatory surgical facilities (Option 6) received mixed support.

In November, staff presented five recommendations to the Commission, based on the Working Paper and our review of the comments received on the Working Paper.

#### **Recommendation 1**

On an interim basis, no changes should be made in ambulatory surgical facilities CON policy. However, a research agenda should be developed to clarify the likely impact of policy alternatives. (See Recommendation 5).

#### **Recommendation 2**

Revisions to the MHCC Ambulatory Surgical Facility Survey should be initiated for the 2001 survey cycle, with appropriate consultation and coordination with the affected providers, to address data deficiencies.

#### **Recommendation 3**

In cooperation with the Department of Health and Mental Hygiene's (the Department) Office of Health Care Quality (OHCQ), research should be undertaken to define the universe of facilities in Maryland which serve as settings for invasive procedures but are not required to obtain licensure under current law and regulation. A white paper outlining the costs and benefits of expanding the scope of freestanding ambulatory surgical facility (FASF) licensure, based on this research, should be developed and distributed for review and comment. MHCC and OHCQ should consider the research and comments and formulate recommendations to the Department concerning the appropriate scope of FASF licensure.

#### **Recommendation 4**

A process should be initiated to develop a consensus among MHCC, OHCQ, and the regulated industry on definitions of "operating room" and "procedure room" to be employed in both CON regulation and licensure.

#### **Recommendation 5**

Research should be conducted to clarify the appropriate direction of CON policy reform with respect to ambulatory surgical facilities. Three areas of research focus are recommended:

- A detailed comparative analysis of the ambulatory surgical services delivery system and the regulatory policies that have shaped those systems in a group of selected states;
- An in-depth analysis of the charge and cost structure of a sample of Maryland FASFs identifying the relationship between costs and charges and characteristics such as range of specialties, type of specialties, volume of procedures, and competitiveness within market service areas;
- A review and analysis of the implications for quality of care of Maryland policies promoting the establishment and operation of low volume, physician-office based surgical facilities.

As implied by these recommendations, staff believes that the Working Paper clearly indicates that Maryland's particular mix of CON policies in the area of ambulatory surgery has produced a unique pattern of FASF development that raises questions with respect to: the economic efficiency of outpatient surgical services delivery in the FASF setting and overall surgical services delivery in the general hospital setting, the population's use of surgical services, the quality of surgical treatment, and equity, both in access to medical care by the population and burden-sharing among medical care providers for the indigent, uninsured, and underinsured.

The Commission invited comment on these recommendations and one written comment was received by the deadline of December 7, 2001.

## **II. Summary of Public Comments on the Staff Recommendation**

The Maryland Ambulatory Surgical Association (MASA) supports the MHCC staff recommendations and offers its assistance in their implementation. (See attached letter from MASA.) With respect to the second recommendation, MASA expresses general concern with the *"expense, time and administrative burden"* placed on facilities through additional data collection requirements and specifically cites the concern of some MASA members that *"public disclosure of certain cost data would allow this information to get into the hands of actual and potential competitors and could also impact their ability to negotiate with payers and employers which contract for services."* However, despite these reservations, MASA is willing to work with MHCC staff in examining the areas where additional data would be useful in understanding the implications of current policy and potential reforms.

## **III. Staff Response and Recommended Action**

MHCC staff affirms its five recommendations of November 15, 2000 and requests that the Commission adopt them as final recommendations.